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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,653	12/04/2000	Biaoyang Lin	P-IS 4367	3087
41552	7590	10/13/2006	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,653

Applicant(s)

LIN, BIAOYANG

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23,26,27 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 26-27 are being examined.

Rejoining of the Method Claims 21-22, 30-32

The response asserts that in the telephonic interview on April 8, 2004, Applicant was informed that a claim directed to a PAMP polypeptide containing the amino acid sequence of SEQ ID NO: 2 would be allowed if rewritten in independent form, but that the broader claim, which encompasses amino acid substitutions relative to SEQ ID NO: 2, would be rejected as allegedly lacking enablement. The response further asserts that the Examiner further proposed several amendments which would put the method of claim 21 in condition for allowance. The response also asserts that Applicant declined to amend the claims at the time of the interview and requested a written action. The response asserts that the claimed PAMP polypeptide in claim 21 is detected in a serum sample, as shown in the Declaration of 10/31/2002, and thus claim 21 is enabled for any sample.

It is noted that the method claim 21 would be rejoined with the product claims 26-27 if the product claims 26-27 were allowable, and if the method claim 21 met the requirements of 112, first paragraph.

Claims 26-27, as presently written, however, are not allowable (see the rejections below), and thus the arguments are moot. MPEP § 804.01 teaches that until all claims to the elected

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product are found allowable, and that to be allowable, the rejoined method claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112, otherwise proper restriction requirement between product claims and process claims may be maintained (see MPEP § 804.01). Since claims 26-27 are presently not allowable, and since rejoining of the method claims is required only at the time of allowance, the method claims 21-22, 30-32 are not considered to be rejoined at this time. Thus the request by Applicant concerning written rejection for claims 21-22, 30-32, and the argument by Applicant concerning the sample issue are moot.

Claim Rejections - 35 USC § 112, First Paragraph, Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amino acid sequence shown as SEQ ID NO:2, does not reasonably provide enablement for **an amino acid sequence having one or more conservative substitutions relative to SEQ ID NO:2**, for reasons already of record in paper of 04/20/04.

The response asserts that one would be able to make and use the claimed PAMP polypeptide comprising an amino acid sequence having one or more conservative substitution relative to SEQ ID NO:2, regardless whether said polypeptide is overexpressed in prostate cancer. The response asserts that an antibody could be prepared against the claimed PAMP polypeptide comprising an amino acid sequence having one or more conservative substitution

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relative to SEQ ID NO:2 can cross-react with SEQ ID NO:2 itself, citing R &D system catalog, 1999, having example of antibody cross-reactivity to related polypeptides. The response asserts that thus the antibody raised against the claimed PAMP polypeptide comprising an amino acid sequence having one or more conservative substitution relative to SEQ ID NO:2 could be used to detect SEQ ID NO:2.

The recitation of R &D system catalog, 1999, is acknowledged and entered.

The response of 08/19/04 has been considered but are not found to be persuasive for the following reasons:

It is noted that a PAMP polypeptide “comprising” is an open language. Further, “an amino acid sequence” reasonably reads on a sequence of any size, including just a two amino acid sequence. “An amino acid sequence having one or more conservative substitutions relative to” SEQ ID NO:2” reasonably reads on any sequence, which does not even have to contain any amino acids of SEQ ID NO:2, except one or two conservative substitutions of the amino acids of SEQ ID NO:2. The claimed amino acid sequence encompasses an unrelated sequence of any size, including having just two amino acids, one of which amino acids is a conservative substitution of an amino acid of SEQ ID NO:2.

Thus the antibody raised against the claimed PAMP polypeptide comprising an amino acid sequence having one or more conservative substitution relative to SEQ ID NO:2 would not cross-react with SEQ ID NO:2, because the two sequences do not even have to share any amino acid, nor an epitope. The antibody raised against the claimed PAMP polypeptide comprising an amino acid sequence having one or more conservative substitution relative to SEQ ID NO:2

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would be non-specific and would detect unrelated sequences, the level of expression of which in prostate cancer is not predictable.

Moreover, even if the claimed amino acid sequence were SEQ ID NO:2 having conservative substitutions, the conservative substituted variants of SEQ ID NO:2 could be substituted at numerous amino acids, throughout the whole length of the sequence, and thus would be structurally completely different from SEQ ID NO:2. In view of such a difference in structure, one cannot predict that the antibody to the claimed amino acid sequence would recognize SEQ ID NO:2, and/or would be specific for SEQ ID NO:2 and would not cross-react with unrelated sequences, the level of expression of which in prostate cancer is not predictable.

New Rejection Based on New Consideration

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Steward CA, 1998, Accession No:046018, of record.

Claim 26 is drawn to: An isolated PAMP polypeptide, comprising an amino acid sequence having one or more conservative substitutions relative to SEQ ID NO: 2.

It is noted that an amino acid sequence having one or more conservative substitutions relative to SEQ ID NO:2 reasonably reads on any amino acid sequence of any length, provided

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that it has one or more amino acids that are conservative substitutions of one or more amino acids of SEQ ID NO:2.

Steward CA teaches a sequence of 519 amino acid in length, which is 45% similar to SEQ ID NO:2, from amino acid 724 to amino acid 1228 of SEQ ID NO:2, and having amino acids that are conservative substitutions of amino acids of SEQ ID NO:2; for example, amino acid D at position 8 of the sequence taught by Steward CA, which is the conservative substitution of amino acid E at position 730 of SEQ ID NO:2 (see MPSRCH 2002 search report, us-09-729-653-2.rspt, page 4, of record).

Conclusion

No claims are allowed.

Claim 27, as drawn to the isolated PAMP polypeptide comprising the amino acid sequence as shown in SEQ ID NO:2, appears to be free of prior art but is **objected to** as being dependent upon a rejected base claim 26, but would be allowable if rewritten in independent forms.

The closest prior art is Steward CA, 1998, *supra*, which teaches a sequence which is only 45% similar to SEQ ID NO:2. The art does not teach or suggest SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
September 27, 2006


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER